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| Office Action Summary | Application No. | Applicant(s) | |
| | 10/541,250 | EL-BAROUDI, FOUAD | |
| | Examiner | Art Unit | |
| | Michael Borin | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 August 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6,8 and 9 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6,8,9 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of Claims

1. Amendment filed 08/17/2009 is acknowledged. Claim 7 is canceled, and the language of claim 7 is incorporated into claim 1. Claims 1-6,8,9 are pending.

2. During interview with applicant's representative, James Livingstone on 12/02/09, Examiner indicated that the claim language as amended is not clear and new grounds of indefiniteness rejections will be necessary to clarify the language before returning to the issue of art rejection.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6,7,9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

- A. Claim 1 is amended to include a step of a correction step making radiograph image data and external acquisition data correspond, the correction step comprising:

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correct the radiograph reconstruction relative to the 3D curve derived from external acquisition data in the same position; and

determine the distribution of points in the 3D curve associated with the vertebrae, positioned in the Stokes coordinate system and their associated tangent

Relation and relevance of this step to other steps of method of claim 1 is not clear. The preceding method steps do not address neither a radiograph image, or a 3D curve, or external acquisition, etc.

B. Claim 1, the step “to personalize the geometry of the said model, using data specific to a patient in the said reference position”. It is not clear what active method steps are being encompassed by this step.

C. Claim 1, step of “personalize the said digital model by particularization of interaction parameters of each joint”. The meaning of the term “interaction parameters” is not clear, and there is no definition of the term in the specification. Not only it is not clear what “interaction parameters” are in general, it is not clear what are the interaction parameters “of each joint”.

D. Claim 1: The term “constraints” is not defined in the claims or specification, and it is not clear what is being encompassed by the term. Further, since it is not clear what a constraint is, it is not clear how a constraint is being determined and applied to a patient.

E. Claim 1 now addresses “determining a mobility or global stiffness resulting from an action of rigid bodies”. It is not clear what action of rigid bodies is meant and how it causes mobility or global stiffness. Note that the original claims were addressing mobility or global stiffness resulting from the “action of insertion elements”, rather than from an action of rigid bodies.

F. Claim 1: the phrase “approximate interaction parameters” is not clear. Specification does not teach any “approximate interaction parameters”. Note, that the original claims were addressing steps to approximate interaction parameters, rather than to determine some “approximate parameters”.

Further, it is not clear how the said “approximate interaction parameters” are related to “interaction parameters” which this method step is supposed to particularize.

G. Claim 1: For the step of “personalize the said digital model by particularization of interaction parameters of each joint”, the last sub-step addressed is “to produce approximate interaction parameters in order to reproduce the measured relative positions”. It is not clear how the unidentified interaction parameters will lead to reproducing relative positions.

H. Claim 1 is amended to recite that “a computer processes a three-dimensional digital model”. It is not clear what “processing” steps are carried out by a computer. Applicant refers to paragraphs 0013, 0046 and 0168 of the printed publication version. However, said sections do not provide description of “processing” steps that are being carried out by a computer.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6,7,9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicant asserts that no New Matter has been added. However, the specification does not appear to provide an adequate written description of the following limitations:

A. "determining a mobility or global stiffness resulting from an action of rigid bodies". Note that the original claims were addressing mobility or global stiffness resulting from the "action of insertion elements", rather than from an action of rigid bodies.

B. "to produce approximate interaction parameters". Specification does not teach any "to produce approximate interaction parameters". Note, that the original claims were addressing steps to approximate interaction parameters, rather than to determine some "approximate parameters".

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations

Claim Rejections - 35 U.S.C. § 101

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

5. Claims 1-6,7,9 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-6,7,9 are drawn to method of simulation of bone joints. The claims do not recite any physical transformation step, nor they recite a tie to another category of invention.

Claim 1 is amended to recite that "a computer processes a three-dimensional digital model". This is the only method step related to use of a machine in the claimed method. However, the claim language does not require use of any particular machine, such as specifically programmed computer; rather, it addresses use of a computer, in general. Further, a step of entering a digital model is viewed as data input, i.e., an insignificant pre-solution activity. Gathering data would not constitute a transformation of any article. A requirement simply that computer processes a three-dimensional digital

mode—without specifying how—is a meaningless limit on a claim to an algorithm because every algorithm inherently requires the input of data.

Conclusion.

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./
Primary Examiner, Art Unit 1631

mlb